

R E M A R K S

1. Claim of Priority

On page 2 of the Office Action, the Office states that “[i]f Applicants wish to receive full benefit of their claim to priority to JP 20030342183, filed September 30, 2003, an English-language translation or equivalent thereof should be filed.”

Applicants note that no English language copy of the priority document is required unless needed for the purpose of overcoming the effective date of a reference. *See e.g.*, M.P.E.P. § 201.15. Thus, an English language translation is not required at this time.

2. Response to the Restriction & Election

The Office restricted claims 1-35 in to one of the following groups:

Group I, claims 1-11 and 31-33, drawn to a method for cleaving a polypeptide having an OmpT cleavage site using a wild-type OmpT; or

Group II, claims 12-30, 34, and 35, drawn to a method for cleaving a polypeptide using a variant OmpT.

2.1 Election of Group II with Traverse

Applicants elect with traverse the claims of **Group II** (*i.e.*, claims 12-30, 34 and 35). Applicants traverse the restriction as the action does not comply with requirements of a restriction requirement for a national stage application. Restriction is *discretionary*. *All* the claims were examined by the International Search Authority. Accordingly there exists an even greater burden above and beyond the serious burden that the Office must evince as to why examining the claims would pose more than a serious burden on the Office. No mention of burden with respect to each of the groups was made.

The Office alleges that serious burden would arise to search claims 1-35 together. Applicants note that unity was found during the examination of the PCT application. No classification was provided to evince differences in classification. No explanation of *why* the claims for the two groups form a separate status in the art was provided. A different field of search is not sufficient to evince serious burden. These are conclusions without corresponding

evidence. When unity is found in the PCT application, there is an *increased burden* above the already “*serious burden*” in evincing why a restriction requirement is necessary. *See* Anthony Caputa, “Two Be or Not To Be: or Divide and Conquer: or A Case Divided Cannot Stand: Principles in Restriction Practice TC 1600,” presented August 2004 to the Customer Partnership Meeting. As stated by Examiner Caputa, “If the inventions, now being restricted, were searched and examined together in either the current application or a parent, it will be difficult to justify the assertion of burden.” T. Caputa, at page 6. Despite the inability to justify a burden of search, the restriction requirement does not address this issue. The restriction accordingly should be duly reconsidered and withdrawn.

Second, the Office appears to have concluded that Group I is directed to wild-type Omp proteases, whereas Group II is directed to variant Omp proteases. If this is the interpretation of the claims, the interpretation and characterization of Group I claims is incorrect. The wild-type Omp protease and the mutant Omp protease are not distinguished in the claims of Group I. Thus, Group II would constitute an improper separation of subject matter, as division of the claims results in an improper separation of now overlapping subject matter. *See* MPEP § 806.03.

Accordingly, the restriction should be reconsidered and withdrawn.

3. The Species Election is Improper

Applicants were further requested to:

- 1) elect one specific OmpT cleavage site if Group I is elected; or
- 2) elect one specific OmpT variant listed in Claims 12-30, 34, and 35 and one specific OmpT cleavage site listed in Claims 12-30, 34 and 35 if Group II is elected.

Applicants elect with traverse the OmpT variant wherein the position 97 is modified to “methionine”. *See* claim 13 for example.

Applicants elect with traverse the cleavage position P1 of arginine.

3.1 The Office Fails to Explain the Procedural Necessity of a Species Election

With regard to Group II the Office is requiring an election of two separate species. The Office does not possess unfettered authority to restrict the claims at its own discretion, even

when a reference allegedly teaches a technical feature that otherwise would provide unity of invention. *See* MPEP § 1850. Even when an independent claim allegedly does not avoid the prior art, the examiner still must consider whether the dependent claims and species recited therein retain “an inventive link”:

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. MPEP § 1850(II), ¶ 8.

Further restriction or species election is justified only if the “remaining subject matter of each claim differs from that of the others.” MPEP § 1850(II), ¶ 4. “[T]he benefit of any doubt is given to the applicant.” *Id.* Notably, in this context, the MPEP states that the “decision with respect to unity of invention rests with the International Search Authority [ISA] or the International Preliminary Examining Authority,” i.e., *not* the examiner of the corresponding National Stage application. *See* MPEP § 1850(II), ¶ 5.

In the present case, the ISA searched *all* the species (and all the claims, for that matter) that the present Examiner would subject to restriction. *See* International Search Report mailed December 28, 2004. Clearly, the ISA did not consider the subject matter of the dependent claims to differ sufficiently from that of the others to warrant a restriction requirement. The determination of unity of invention rests with the ISA, who in this case *searched all the claims*. *See* MPEP § 1850(II), ¶ 5. Properly giving Applicants the benefit of the doubt, the Examiner should rejoin and examine *at least* all the recited species. *See* MPEP § 1850(II), ¶ 4.

Further, restriction is proper only if the inventions are independent or distinct as claimed *and* there would be a serious burden on the examiner if restriction were not required. *See* MPEP §§ 803, 808; *see also* MPEP § 808.02 (establishing burden). Applicants’ previous arguments with respect to the burden of search is incorporated here by reference. How can the Office allege that the burden of search is *serious* when the ISA *already has searched* all the claimed subject matter?

In the context of burden of search, the Office alleges that the alleged inventions have acquired a different status in the art, are directed to recognized divergent subject matter, would require a different search, etc. The Office, however, merely states the accepted criteria for justifying restriction. The Office provides no evidence supporting any of the allegations. The

Office's own Manual of Classification groups the sequences into the same class and subclass. They are in fact based on the same sequence. Thus, even the Office recognizes that the sequences are properly the subject of a single search of the art. The Office fails to provide evidence that OmpT variants would require separate searches of the relevant art, for example.

3.2 The Office Fails to Evince Any Burden Let Alone Serious Burden

Species election is proper only if the inventions are independent or distinct as claimed, and there would be a *serious burden* on the examiner if restriction were not required. *See* MPEP §§ 803, 808; *see also* MPEP § 808.02 (establishing burden). How can the Office allege that the burden of search is *serious* when the International Search Authority *already has searched* all the claimed subject matter, including the species?

3.3 Restriction Would Result in Division of Overlapping Subject Matter

Applicants note further that the species are recited in dependent claims. MPEP § 806.04(f) states "to require restriction between claims limited to species, the claims must not overlap in scope." At the very least, MPEP § 806.04(f) requires the Examiner to justify why claims issuing on the allegedly separate and distinct species would not overlap in scope. *See also* MPEP § 806.05 ("Related inventions in the same statutory class are . . . not overlapping in scope, if a first invention would not infringe a second invention, and the second invention would not infringe the first invention."). The Office is totally silent in this regard.

Regarding the election of the P1 species, it is without substantive support for the purpose of how this forms a separate and distinct invention. The variant interacts with a cleavage site P1 of a substrate. Stated differently, substrate specificity does depend on which residue resides at the 97th amino acid position. However, the substrate specificity is inherent to the variant. You cannot elect that which is inherent. Thus, the requirement or the election is irrelevant, regardless of the election made. Nineteen types of variants were prepared at the 97th position. All were tested. These species form a genus. The genus is described and should be kept together for the reasons discussed above.

Additionally, Applicants note that specifying P1 is further inappropriate, because the protease acts on two continuous basic amino acids. Therefore, it acts on Arg and/or Lys.

Therefore, Arg and Lys are equivalent at P1. The action of the variant on the substrate is inherent to the variant and cannot be made the subject of a species election.

Applicants respectfully request reconsideration and withdrawal of both the restriction requirement and the election requirement.

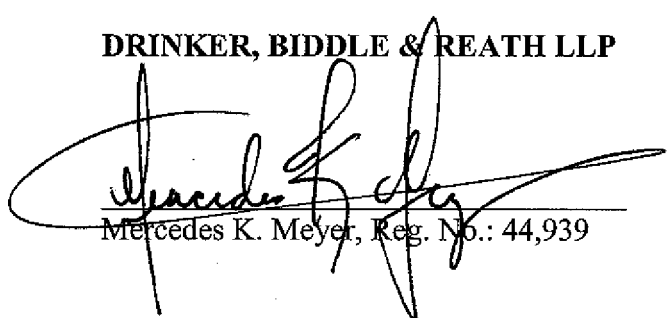
CONCLUSION

If there are any other fees due in connection with the filing of this Preliminary Amendment, please charge the fees to our Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: November 21, 2008



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